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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,491

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Wenping Wu

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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,491	Applicant(s) WU ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 11-14, 16-20, 23-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 14, 16-20, 23 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-20, 23, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' response of October 29, 2008, to the action of April 7, 2008, is acknowledged. It is acknowledged that Claim 10 has been cancelled and Claims 1-5, 7, 11-13, 24, and 25 have been amended. Claims 1-5, 7, 11-14, 16-20, 23-25, and 27 are pending. Claims 14, 16-20, 23, and 27 were previously withdrawn, as being drawn to nonelected inventions. Claims 14, 16-20, 23, and 27 are hereby examined.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claim 5, because it is unclear whether the phrase "comprising a substitution ...of one or more amino acid residues" modifies the parent protease or the variant protease, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that the claim terminology is clear; the specification clearly sets forth the protease modifications and variants according to the invention. See, e.g., p. 5, lines 7-20. This argument is not found to be persuasive for the following reasons. It is acknowledged that said lines of the specification state:

"The term "modification(s)" used herein is defined to include chemical modification of a protease as well as genetic manipulation of the DNA encoding a protease. The modification(s) can be replacement(s) of the amino acid side chain(s), substitution(s), deletion(s) and/or insertions in or at the amino acid(s) of interest."

However, said statement fails to define whether the phrase "comprising a substitution ...of one or more amino acid residues" in Claim 5 modifies the parent protease or the variant protease.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1, 2, 5, 7, 11-13, 24, and 25 under 35 U.S.C. 112, first paragraph/enablement, for reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following argument. That the amended claims, which are directed to isolated proteases comprising an amino acid sequence which has at least 90% identity with residues 1 to 226 of SEQ ID NO: 2, are fully enabled by the specification. This argument is not found to be persuasive for the following reasons. As explained in the prior action, by use of “comprising” language, these claims encompass proteases wherein the activity is not derived from the sequence homologous to SEQ ID NO: 2. The specification fails to enable the skilled artisan to make and use the full scope of said proteases.

Written Description

Rejection of Claims 1, 2, 5, 7, 11-13, 24, and 25 under 35 U.S.C. 112, first paragraph/written description, for reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. The amended claims are directed to isolated proteases comprising an amino acid sequence which has at least 90% identity with residues 1 to 226 of SEQ ID NO: 2 and having protease activity. The specification provides an actual reduction to practice of a protein comprising SEQ ID NO: 2 and describes the complete structure of SEQ ID NO: 2. See, e.g., Sequence Listing for SEQ ID NO: 2. The specification also describes the function of the claimed protease; i.e., protease activity.

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(see, e.g., Examples II and IV). Moreover, all of the claimed proteases share a high degree of structural similarity to SEQ ID NO: 2 (i.e., at least 90% of SEQ ID NO: 2).

This argument is not found to be persuasive for the following reasons. As explained in the prior action, by use of “comprising” language, these claims encompass proteases wherein the activity is not derived from the sequence homologous to SEQ ID NO: 2. The specification fails to describe any such proteases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1-5, 7, 10-13, and 24 under 35 U.S.C. 102(b) as being anticipated by Isono et al, 1972 as evidenced by Isono et al, 1972 and Esaki et al, 1994, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that none of these references disclose or suggest the proteases recited in the claims as amended herein. Applicants’ “argument” is a mere assertion without any reasoning. Therefore, the Office is not able to provide counter arguments. The reasons the Office believes the protease of Isono et al is the same as the protease set forth by SEQ ID NO: 2 herein are explained in the prior action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al, 1972 in view of Okuda et al, 2004 (FD 12-MAR-2003), for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that none of these references disclose or suggest the proteases recited in the claims as amended herein. Applicants' "argument" is a mere assertion without any reasoning. Therefore, the Office is not able to provide counter arguments. The reasons the Office believes the protease of Isono et al, is the same as the protease set forth by SEQ ID NO: 2 are explained in the prior action.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652